



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,131	11/22/2000	Ralph L. Bass	1136/8	2281

24239 7590 03/21/2003

MOORE & VAN ALLEN, PLLC
2200 W MAIN STREET
SUITE 800
DURHAM, NC 27705

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application N .

09/721,131

Applicant(s)

BASS, RALPH L.

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 27 February 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8.
10. ☐ Other: _____

JOHN BAK
PRIMARY EXAMINER
GROUP 1200

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that Examiner has argued reasons for a 112 1st paragraph rejection, however, Examiner has simply provided reasons why the claimed invention lacks credible utility. Applicant provides a Merck reference disclosing the mechanism of action on HIV infection of CD4 T-cells and CRIVAN® and concludes that one of ordinary skill in the art would expect that an HIV attached to a CD4 T-cell acts differently from free HIV cells in phosphate buffered saline, presumably that the HIV attached to a CD4 T-cell would be susceptible to rupture at lower concentrations of NaCl. However, Applicant does not appear to provide sufficient evidence as to why one of ordinary skill in the art would conclude from the Merck manual that an HIV attached to a CD4 T-cell would act differently from free HIV in phosphate buffered saline. Applicant's reliance on *In Re Cortright* is misplaced. *In Re Cortright*, although it did discuss utility, was decided against the Patent applicant on a 112 issue. Further, with respect to the discussion of utility, the court indicated that although the mechanism by which the invention worked was unknown or mistaken by the inventor there were actual results obtained and the case involved treatment of baldness which according to the Court has gained acceptance (Pg. 1468,1469). In this case, Examiner is rejecting under 35 USC 101 because the claimed invention lacks credible utility in that a method of alleviating HIV infection by administration of NaCl is inherently suspect or involves implausible scientific principles as supported by the reasons set forth in the prior Office Action. With respect Claim 35, it is true that Applicant has disclosed methods of transdermal administration but Examiner reiterates that Applicant has claimed transdermal administration which is through the skin but the claimed invention is administration in the upper GI tract which does not have skin but a mucosa. Applicant's citation to US Pat. 5,026,652 does not overcome the rejection as again administration through the skin is disclosed and does not disclose the transdermal administration of NaCl in the amounts required by the claimed invention. As such in light of the evidence that there is no transdermal uptake of NaCl by the skin, Applicant's disclosure does not appear sufficient to enable one of ordinary skill in the art to transdermally administer NaCl in the amount necessary to arrive at the claimed therapeutic amounts..